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Pabst Patent Group LLP
1545 PEACHTREE STREET NE
SUITE 320
ATLANTA, GA 30309

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARVIN J. SLEPIAN

Appeal 2009-011539
Application 10/072,766
Technology Center 1600

Decided: June 14, 2010

Before TONI R. SCHEINER, DONALD E. ADAMS, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 by the Patent Applicant from the Patent Examiner's rejections of claims 1, 3, 6, 7, 13, 15-25, 28, 29, 31-33, and 35-37. The Board's jurisdiction for this appeal is under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

The claims are directed to methods and devices for treatment involving cutting or removing tissue from the endomural zone in an organ to create a void and delivering an agent into the void. The "endomural zone" is the middle region of the three different regions found in an organ (Spec. 6:1-15).

Claims 1, 3, 6-13, 15-33, and 35-37 are pending. Claims 2, 4, 5, 14, and 34 are canceled. Claims 8-12, 26, 27, and 30 are withdrawn. Claims 1, 3, 6, 7, 13, 15-25, 28, 29, 31-33, and 35-37 are appealed and stand rejected by the Examiner as follows:[1]

Claims 1, 3, 6, 7, 15-18, 20-23, 25, 28, 29, 32, and 35-37 under 35 U.S.C. § 102(e) as anticipated by Altman[2] '716 (Ans. 3);

Claims 1, 3, 6, 7, 15-19, 21-23, 25, 36, and 37 under 35 U.S.C. § 102(e) as anticipated by Altman[3] '887 (Ans. 5);

Claims 1, 3, 6, 7, 15, 16, 18, 20-24, 32, and 35-37 under 35 U.S.C. § 102(e) as anticipated by Haim[4] (Ans. 7);

Claims 13 and 33 under 35 U.S.C. §103(a) as obvious in view of Altman '716, Altman '887 or Haim; and Benjamin and McMillan[5] (Ans. 8); and

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[1] Canceled claims were included in the Examiner's statements of the rejection. We have modified the statements to reflect the correct status of the claims.
[2] Altman, US 6,585,716 B2, issued Jul. 1, 2003.
[3] Altman, US 6,102,887, issued Aug. 15, 2000.
[4] Haim et al., US 6,309,370 B1, issued Oct. 30, 2001.
[5] Ivor J. Benjamin and D. Randy McMillan, *Stress (Heat Shock) Proteins Molecular Chaperones in Cardiovascular Biology and Disease* 83 CIRC RES. 117-132 (1998).

Claim 31 under 35 U.S.C. §103(a) as obvious in view Brösamle[6]; and Altman '716, Altman '887 or Haim (Ans. 9).

Claim 1 and 15 are illustrative and read as follows:

1. A method of treatment comprising

(a) penetrating into the endomural zone of an organ, organ component or tissue structure,

(b) cutting or removing tissue in the endomural zone to create a void, cavity, containment space or reservoir area, and

(c) delivering a therapeutic, prophylactic or diagnostic agent to the void, cavity, containment space or reservoir area in the endomural zone, wherein the agent is in a polymeric material for local delivery of an effective amount of the therapeutic, prophylactic or diagnostic agent to the endomural zone,

wherein the polymeric material is selected from the group consisting of porous matrices, hydrogels, organogels, colloidal suspensions, and combinations thereof.

15. A device comprising

a hollow tubular member with an end means for creating a void, cavity, containment space or reservoir area in the endomural zone of an organ, organ component or tissue structure, by cutting or removal of tissue, wherein the means for creating the void, cavity, containment space or reservoir area is designed to cause minimal collateral damage to tissue surrounding a site where the void, cavity, containment space or reervoir [sic] is created,

and means for local delivery of a therapeutic, prophylactic or diagnostic agent into the void, cavity, containment space or reservoir area, wherein the agent is delivered in a polymeric carrier selected from the group consisting of porous matrices, hydrogels, organogels, colloidal suspensions, and combinations thereof,

the device further comprising means for indirect or direct guidance.

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[6] Brösamle et al., *Regeneration of Lesioned Corticospinal Tract Fibers in the Adult Rat Induced by a Recombinant, Humanized IN-1 Antibody Fragment* 20 J. NEUROSCIENCE 8061-8068 (2000).

ANTICIPATION BY ALTMAN '716

Claims 1, 3, 6, 7, 15-18, 20-23, 25, 28, 29, 32, and 35-37 stand rejected under 35 U.S.C. § 102(e) as anticipated by Altman '716 (Ans. 3).

Statement of the issues

Appellant contends that Altman '716 fails to describe the following steps or elements recited in the claims:

Claims 1, 3, 6, 7, and 35-37

• does not disclose "forming a void, cavity, containment space or reservoir in the endomural zone" by a separate step of cutting and/or removing (App. Br. 9; Reply Br.[7]);

• does not create a void into which polymeric material is implanted and retained (App. Br. 10); and

• does not disclose delivering to the endomural zone (Reply Br.).

Claims 15

• does not describe a separate means for creating a void and separate means for local delivery of a therapeutic agent (Reply Br.).

Claim 20

• does not describe a device with diagnostic or therapeutic sensors (App. Br. 11).

Claims 21-22

[7] All the pages of the Reply Brief were numbered "13."

• does not describe a projectile means to ballistically transfer particles into the endomural zone (App. Br. 11).

Claim 23

• does not describe a device with means for direct guidance (App. Br. 11).

Claims 25, 28, 29, and 32

• does not disclose an element for creating a void (Reply Br.); and

• does not disclose void filling material or implant in a form suitable for delivery (Reply Br.).

Principles of Law

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke, supra*. Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *See In re Brown*, 459 F.2d 531, 59 CCPA 1036, 173 USPQ 685 (1972).

In re Best, 562 F.2d 1252, 1255 (CCPA 1977).

"[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990).

Facts ("F") in Altman '716

1. Altman '716 describes devices and methods "for delivery of therapeutic substances to a depth within the heart muscle" (Altman '716, at col. 3, ll. 2-4).

2. Altman '716 describes the use of a "guide catheter . . . to guide the drug delivery catheter" to the target site (*id.* at col. 4, ll. 11-19 & 52-62; col. 5, ll. 16-23).

3. "The catheter distal tip 24 includes a penetrating element 28, for example a curved or helical needle" which "is forced through the wall of the vein, and into the myocardium. Therapeutic agents are then injected into the myocardium through the catheter and needle" (*id.* at col. 4, ll. 13-19).

4. "To enhance the retention of the therapeutic agents in the needle track and/or within the myocardium in the face of natural fluid flow from the myocardium into the vein," the vein flow can be shut off by an occluding mechanism (*id.* at col. 4, ll. 20-26; *see also* col. 5, ll. 56-57).

5. Therapeutic agents may be "slowly injected at a rate of about 0.1 milliliters per minute." (*Id.* at col. 5, ll. 58-60.)

6. "The devices and methods may be combined with permanently implantable devices with and without the electrical sensing and stimulation capabilities, and they provide either sustained delivery . . . or they may deliver fluid agents upon demand as a result of an event sensed by a patient" (*id.* at col. 5, l. 65-col. 6, l. 4).

7. The therapeutic agents can be delivered in controlled release matrices, such as "polymeric matrices" and "hydro gels" (*id.* at col. 6, ll. 8-10).

Analysis

Claims 1, 3, 6, 7, and 35-37

Claim 1, which is representative, is directed to a treatment method comprising steps in which (a) the endomural zone is penetrated, "(b) cutting or removing tissue in the endomural zone to create a void, cavity, containment space or reservoir area," and (c) delivering the agent to the "void, cavity, containment space or reservoir area" in the endomural zone. Claims 3, 6, 7, and 35-37 depend directly or indirectly on claim 1. The Examiner found that all the steps and elements of the claim were described by Altman '716. Appellant challenges the Examiner's determination.

Appellant contends that Altman '716 does not disclose forming a void, cavity, containment space or reservoir in the endomural zone by a separate step of cutting and/or removing nor a void into which polymeric material is implanted and retained (App. Br. 9; Reply Br.).

We do not agree. Altman '716 explicitly describes "retention of the therapeutic agents in the needle track." (F4.) The track is a void as in claim 1. Persons of ordinary skill in the art would have recognized that the track is created by the penetrating element 28 since element 28 is the device through which the therapeutic agents are delivered (F4). As the penetrating element can be a needle (F3), and it has the ability to penetrate tissues (F3), the Examiner had sound basis to believe that it would "cut" tissue as required by claim 1. In sum, the needle cuts into the tissue to create a void as required by step (b) of claim 1.

In step (c), the agent is delivered into the void. Altman' 716 also describes this step. Altman '716 refers to "retention of the therapeutic agents in the needle track." (F4.) In other words, upon removal of the

needle from the tissue, the void ("needle track") becomes filled with therapeutic agent ("(c) delivering a therapeutic . . . agent to the void" as in claim 1) and then the agent is retained in the void.

Appellant contends that "Altman ['716] instead injects into the tissue, not removing any tissue . . . since the tissue has merely been pushed aside by the needle" (App. Br. 11).

This argument is not persuasive since claim 1 does not require that tissue be removed. Claim 1 recites "cutting or removing tissue . . . to create a void." The Examiner had sound basis to believe, which Appellant has not rebutted, that the Altman '716 needle cuts into the tissue to create a needle track – the "void" of claim 1.

Appellant also contends that Altman '716 does not disclose delivering agent to the heart's endomural zone (Reply Br. 13). As recognized by Appellant, Altman '716 delivers substances "to a depth within the heart muscle." (F1). Based on this disclosure, the Examiner had sound factual basis to believe that therapeutic agent was delivered into the endomural region, shifting the burden to Appellant to rebut it. Appellant did not provide any evidence to the contrary.

Claims 15-18

Claim 15 is directed to a device which comprises means for creating a void, cavity, containment space or reservoir area, means for local delivery of therapeutic, prophylactic or diagnostic agent, and means for indirect or direct guidance. Claims 16-18 depend on claim 15.

Appellant contends that Altman '716 does not describe separate elements for creating the void and for delivering the agent (Reply Br.). This

argument is not supported by the evidence. Altman '716 describes a needle, a device which was used to create a void ("needle tracks") by cutting (F3 & F4) and an implantable device to provide sustained delivery (F6; Ans. 12). Therefore, Altman describes a device with both claimed elements.

Appellant contends that the "if the penetrating element (element 28) cut or removed tissue, the tissue would clog the needle and prevent the delivery of the therapeutic" (Reply Br.). This argument is not persuasive. As noted above, Altman '716 described a separate device for drug delivery (F6).

Claim 20

Claim 20 is directed to the device of claim 15, further comprising "diagnostic or therapeutic sensors." Contrary to Appellant's contention, Altman '716 describes a device with "electrical sensing" as part of its delivery system (F6), meeting the limitation of claim 20.

Claims 21-22

Claim 21 is directed to the device of claim 15, further comprising "projectile means to ballistically transfer particles through the ectoluminal or endoluminal zone for retention in the endomural zone." Claim 22 depends on claim 22.

The Examiner found that the latter limitation was met by Altman '716's disclosure of injection which "requires mechanical acceleration" (Ans. 12; F3 & F5). Appellant did not identify a deficiency in this finding.

Claim 23

Claim 23 is directed to the device of claim 15, further comprising "means for direct guidance."

The Examiner found the limitation recited in claim 23 to have been met by the disclosure of a guide catheter (Ans. 4 & 12; F2). Appellant did not identify a deficiency in this finding.

Claims 25, 28, 29, and 32

Claim 25 is drawn to a kit comprising a device, where the device comprises a hollow tubular member, a means for creating a void, cavity, containment space or reservoir area, a means for local delivery of therapeutic, prophylactic or diagnostic agent, and "a void filling polymeric or implant . . . in a form suitable for local delivery." Claims 28, 29, and 32 depend directly or indirectly on claim 25.

Appellant contends that Altman '716 does not disclose the means for creating a void and a void filling material. The presence of the void has been addressed already. As to the "void filling polymeric material," Altman '716 describes "polymeric matrices" (F7) meeting the corresponding limitation of the claim. Appellant did not explain why this disclosure did not meet the claimed element.

ANTICIPATION BY ALTMAN '887

Claims 1, 3, 6, 7, 15-19, 21-23, 25, 36, and 37 stand rejected under 35 U.S.C. § 102(e) as anticipated by Altman '887 (Ans. 5).

Statement of the issues

Appellant contends that Altman '887 fails to describe the following steps or elements recited in the claims:

Claim 1

• does not describe creating a void (App. Br. 12).

Claim 19

• does not describe an expansile cutter (Reply Br.).

Claims 21-22

• does not describe a projectile means to ballistically transfer particles into the endomural zone (App. Br. 11).

Claim 23

• does not describe a device with means for direct guidance (App. Br. 11).

Claims 25

• does not disclose an element for creating a void (Reply Br.); and

• does not disclose void filling material or implant in a form suitable for delivery (Reply Br.).

Facts of Altman '887

8. Altman '887 describes a drug delivery device with a penetrating element coupled to a drug reservoir so that drugs and other therapeutic agents can be

injected through the penetrating element and into the body tissue (Altman '887, col. 3, ll. 9-15).

9. The penetrating structure can be a hollow needle and other needle structures (*id.* at col. 4, ll. 5-15).

10. The catheter is navigated to the tissue, for example, using a steerable catheter handle (*id.* at col. 3, ll. 15-17; col. 4, ll. 16-36).

11. Altman '887 describes a catheter with a hollow needle and an expanding prong fixation system with prongs 860 and 870 to "grasp the body tissue" and hold the needle at a depth within the target body tissue (*id.* at col. 9, ll. 22-52; col. 10, ll. 5-21).

12. Altman '887 teaches that the fluid in the fluid delivery tube "is pressurized and driven through" the needle (*id.* at col. 6, ll. 45-47). Altman '887 discloses that osmotic pumps, controlled release matrices, and piston chambers can also be used (*id.* at col. 6, ll. 50-67).

13. Polymer matrices and microspheres are described by Altman '887 as useful for delivery of therapeutic agents with its system (*id.* at col. 12, ll. 25-39).

Analysis

Claims 1, 3, 6, and 7

Method claims 1, 3, 6, and 7 require cutting or removing tissue to create a void and delivering a therapeutic agent into the void. The Examiner did not provide sufficient evidence that Altman '887 taught therapeutic agent delivery into a void. Consequently, we reverse the rejection of these claims.

Claims 19

Claim 19 is directed to the device of claim 15, "wherein the means to create the void, cavity, containment space or reservoir comprises an expansile cutter attached to an end of the member." The Examiner found that this element was met by Altman '887's prong fixation device (F11).

Appellant contends that Altman '887's disclosure of a pronged fixation device (Ans. 5-6) is not an expansile cutter. Appellant contends:

> The fixation system is designed to stay in place as the agent is delivered. The '887 patent does not disclose retracting the prongs prior to delivery of an agent. Thus, the prongs of the fixation system disclosed in the '887 patent do not create a void, cavity, containment space or reservoir into which the agent is delivered.

(App. Br. 13.)

Appellant's argument is consistent with the description of the prongs in Altman '887 (F11). The prongs fix the needle in the tissue without creating a void. (*See* Spec. 11:21-25, where expansile cutter systems are distinguished from trochars and needles.) Consequently, we reverse this rejection.

Claims 21-22

Claim 21 is directed to the device of claim 15, further comprising "projectile means to ballistically transfer particles through the ectoluminal or endoluminal zone for retention in the endomural zone." Claim 22 depends on claim 21.

The Examiner found that the latter limitation was met by the Altman '887 disclosure of injection with piston chamber which "requires mechanical

acceleration" (Ans. 12; F12). Appellant did not identify a deficiency in this finding.

Claim 23

Claim 23 is directed to the device of claim 15, further comprising "means for direct guidance."

The Examiner found the limitation recited in claim 23 to have been met by the disclosure of a guide catheter (Ans. 6 & 12; F8 & F10). Appellant did not identify a deficiency in this finding.

Claims 25

Claim 25 is drawn to a kit comprising a device, where the device comprises a hollow tubular member, a means for creating a void, cavity, containment space or reservoir area, a means for local delivery of therapeutic, prophylactic or diagnostic agent, and "a void filling polymeric material or implant . . . in a form suitable for local delivery."

Appellant contends that Altman '887 does not disclose the means for creating a void and a void filling material. The means for creating a void is met by the penetrating hollow needle (F9). The Examiner explained how the needle met the claimed means (Ans. 6). Appellant did not point to a deficiency in the Examiner's reasoning which was fact-based and supported by evidence. We adopt it as our own.

As to the "void filling polymeric material," Altman '887 describes "polymeric matrices" (F13), meeting the corresponding limitation of the claim. Appellant did not explain why this disclosure did not meet the claimed element.

ANTICIPATION BY HAIM

Claims 1, 3, 6, 7, 15, 16, 18, 20-24, 32, and 35-37 stand rejected under 35 U.S.C. § 102(e) as anticipated by Haim (Ans. 7).

Statement of the issues

Appellant contends that Haim fails to describe the following steps or elements recited in the claims:

Claims 1, 3, 6, 7, and 35-37

• does not disclose forming a void, cavity, containment space or reservoir in the endomural zone by cutting and/or removing (App. Br. 14; Reply Br.); and

• does not disclose delivering to the endomural zone (Reply Br.).

Claim 15

• does not describe a needle to which creates a void (Reply Br.).

Claim 20

• does not describe a device with diagnostic or therapeutic sensors (App. Br. 11).

Claims 21-22

• does not describe a projectile means to ballistically transfer particles into the endomural zone (App. Br. 11).

Claim 23

• does not describe a device with means for direct guidance (App. Br. 11).

Facts ("F") in Haim

14. Haim describes an intracardiac delivery device comprising a catheter to deliver drugs to the myocardium at an appropriate depth (Haim, col. 3, ll. 43-55).

15. The catheter comprises a position sensor to navigate and position the catheter at one or more locations (*id.* at col. 3, ll. 48-50), and can include a steering mechanism (*id.* at col. 4, ll. 11-24). *See also id.* at col. 8, ll. 57-62.

16. The device can comprise hollow needles to deliver drugs (*id.* at col. 5, ll. 20-26).

17. The device can comprise various sensor types, such an occlusion detector, and an ultrasound sensor (*id.* at col. 5, ll. 55-60 & col. 6, ll. 16-18).

18. Haim also describes the device as comprising a laser which is "operated to produce LMR channels in the myocardium, and a dose of the growth factor is then inserted into some or all of the channels" (*id.* at col. 6, ll. 40-46 & l. 66-col. 7, l. 1).

19. Haim also teaches a radiation source and administering "drug into a channel produced in the tissue by the irradiation" (*id.* at col. 8, ll. 16-22).

20. Haim teaches different types of fluid metering pumps to deliver drugs, such as a piston and peristaltic pump (*id.* at col. 13, ll. 1-13).

Analysis

Claims 1, 3, 6, 7, 15, & 35-37

Appellant contends that Haim does not disclose forming a void, cavity, containment space or reservoir in the endomural zone by cutting and/or removing nor delivering to the endomural zone (App. Br. 14; Reply Br.). This argument applies to both claims 1 and 15.

We do not agree. The Examiner found that Haim expressly taught using a laser to produce "channels" which serve as voids (Ans. 7). This finding is supported by Haim's disclosure which describes laser made channels (F18) and also channels produced by irradiation (F19).

Appellant also contends that Haim does not disclose delivering a therapeutic agent to the endomural zone (Reply Br.). Appellant states that "preferably the needle extends 2-3 mm beyond the tip" and that using "such a depth would result in shallow delivery of the therapeutic agent to the myocardium" (*id.*).

The Examiner found that Haim taught delivering drugs into the myocardium tissue by needle and laser (Ans. 7). As the drug is delivered into the myocardial tissue, the Examiner had a sound basis to believe that some would be delivered to the endomural region. Appellant did not provide evidence to rebut this. For example, Appellant argues that the preferred depth of injection was to 2-3 mm, but did not provide evidence that this depth would not include endomural region as claimed. Moreover, Appellant did not address Haim's disclosure of creating laser channel voids to deliver drugs, a teaching separate from the needle delivery disclosure.

Claim 20

Claim 20 is directed to the device of claim 15, further comprising "diagnostic or therapeutic sensors." Contrary to Appellant's contention, Haim describes sensors as part of its delivery system (F17), meeting the limitation of claim 20.

Claims 21-22

Claim 21 is directed to the device of claim 15, further comprising "projectile means to ballistically transfer particles through the ectoluminal or endoluminal zone for retention in the endomural zone."

The Examiner found that the latter limitation was met by Haim's disclosure of a piston pump (Ans. 13; F20), a fact not disputed by Appellant.

Claim 23

Claim 23 is directed to the device of claim 15, further comprising "means for direct guidance."

Haim describes structures to guide its catheter (F15). Appellant's position is contrary to Haim's explicit disclosure.

OBVIOUSNESS

Claims 13 and 33 stand rejected under 35 U.S.C. §103(a) as obvious in view of Altman '716, Altman '887 or Haim; and Benjamin and McMillan (Ans. 8); and

Claim 31 stands rejected under 35 U.S.C. §103(a) as obvious in view Brösamle; and Altman '716, Altman '887 or Haim (Ans. 9).

We adopt the Examiner's findings and affirm the rejections for the reasons set forth by the Examiner on pages 8-10 of the Answer.

SUMMARY

The anticipation rejection of claims 1, 15, 20, 21, 23, and 25 by Altman '716 is affirmed. Claims 3, 6, 7, 16-18, 22, 28, 29, 32, and 35-37 fall with the latter claims because separate reasons for their patentability were not provided. *See* 37 C.F.R. § 41.37(c)(1)(vii).

The anticipation rejection of claims 1, 3, 6, 7, and 19 by Altman '887 is reversed.

The anticipation rejection of claims 21, 23, and 25 by Altman '887 is affirmed. Claims 15-18, 22, 36, and 37 fall with the latter claims because separate reasons for their patentability were not provided. *See* 37 C.F.R. § 41.37(c)(1)(vii).

The anticipation of claims 1, 15, 20, 21, and 23 by Haim is affirmed. Claims 3, 6, 7, 16, 18, 22, 24, 32, and 35-37 fall with the latter claims because separate reasons for their patentability were not provided. *See* 37 C.F.R. § 41.37(c)(1)(vii).

The obviousness rejections of claims 13, 31, and 33 are affirmed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

cdc

Pabst Patent Group LLP
1545 PEACHTREE STREET NE
SUITE 320
ATLANTA, GA 30309